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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,682	08/27/2001	David E. Townsend	150026.464	4343

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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,682

Applicant(s)

TOWNSEND, DAVID E.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment filed October 7, 2003 has been received and entered into the case. Claim 9 has been canceled. Claims 1 – 8 and 10 – 16 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Objections

1. Claim 4 remains objected to because of the following informalities:

The term "Cryptosporidium" should be correctly spelled "Cryptosporidium". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Rejections under 35 U.S.C. 112, second paragraph, have been withdrawn due to amendment.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1 – 6 and 8 – 15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Townsend.

Applicant claims a composition comprising a conditionally detectable marker that provides a detectable signal upon contact with a viable microorganism, and a substrate for an aminopeptidase that is substantially absent from a target microorganism. The target microorganism is a bacteria, yeast, mold, fungi, protozoa or virus, specifically bacteria selected from Salmonella, Listeria, E. coli OH157, Campylobacter, Staphylococcus aureus, Cryptosporidium or Giardia. The preferred bacteria are Campylobacter. The conditionally detectable marker is detectable by a color change. The substrate comprises a signal moiety linked to the substrate that provides a detectable signal when cleaved by substantially all non target microorganisms. The enzyme is specifically L-alanine aminopeptidase; and the substrate is selected from a disclosed group, specifically l-alanine-7-amido-4-methylcoumarin. The non target microorganisms are substantially all non-Campylobacter species. The composition further comprises a growth supporting medium for target microorganisms, which contains all necessary nutrients and growth conditions to support target organism.

Townsend teaches a composition for detecting viable bacteria, yeasts or fungi (p.11) in a test sample, the composition comprising substrates and detectable markers (abstract). Townsend teaches examples of detectable markers include tetrazolium that is chemically reduced to produce a color change (p.2) and bacterial substrates that change color or fluoresce upon bacterial hydrolysis (p.6, 9), or are conditionally detectable markers. Bacteria are selected from

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Staphylococcus aureus, E. coli, and gram negative bacteria of Bergey's Manual of Systematic Bacteriology, 1989 (p.8-9) (includes Salmonella, Listeria, Campylobacter, Cryptosporidium, S. aureus). Townsend teaches the claimed substrates (p.19), preferring L-alanine-7-amido-4-methylcoumarin, and L-alanine-aminopeptidase as the enzyme (p.9). The composition further comprises the nutrients necessary to support growth of the microorganisms (p.3).

Although Townsend does not teach each functional limitation of the claims, the compositions are the same. As such the composition of Townsend must intrinsically exhibit the claimed functional properties. Therefore, the reference anticipates the claimed subject matter.

Applicant argues that Townsend does not teach every element of the claim, that Townsend merely teaches a laundry list of enzymes that could be used with organisms that have the enzyme, and that the aminopeptidase must be absent the target microorganism.

However, these arguments fail to persuade because Townsend specifically teaches the claimed enzyme and substrate as the preferred enzyme (p.6, 10 and claims). Further, since the reference composition contains the same components as the claims, the compositions are the same. It is noted that while Townsend does not teach that the composition can be used in the manner instantly claimed, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art

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appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1 – 8 and 10 – 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend.

Applicant claims a composition comprising a conditionally detectable marker that provides a detectable signal upon contact with a viable microorganism, and a substrate for an aminopeptidase that is substantially absent from a target microorganism. The target microorganism is a bacteria, yeast, mold, fungi, protozoa or virus, specifically bacteria selected from Salmonella, Listeria, E. coli OH157, Campylobacter, Staphylococcus aureus, Cryptosporidium or Giardia. The preferred bacteria are Campylobacter. The conditionally detectable marker is detectable by a color change, wherein the change in color is produced by a biochemical reduction of tetrazolium red. The substrate comprises a signal moiety linked to the substrate that provides a detectable signal when cleaved by substantially all non target microorganisms. The enzyme is specifically L-alanine aminopeptidase; and the substrate is selected from a disclosed group, specifically L-alanine-7-amido-4-methylcoumarin. The non-

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target microorganisms are substantially all non-Campylobacter species. The composition further comprises a growth supporting medium for target microorganisms, which contains all necessary nutrients and growth conditions to support target organism.

Townsend teaches a composition for detecting viable bacteria, yeasts or fungi (p.11) in a test sample, the composition comprising substrates and detectable markers (abstract). Townsend teaches examples of detectable markers include tetrazolium that is chemically reduced to produce a color change (p.2) and bacterial substrates that change color or fluoresce upon bacterial hydrolysis (p.6, 9), or are conditionally detectable markers. Bacteria are selected from *Staphylococcus aureus*, *E. coli*, and gram negative bacteria of Bergey's Manual of Systematic Bacteriology, 1989 (p.8-9) (includes *Salmonella*, *Listeria*, *Campylobacter*, *Cryptosporidium*, *S. aureus*). Townsend teaches the claimed substrates (p.19), preferring L-alanine-7-amido-4-methylcoumarin, and L-alanine-aminopeptidase as the enzyme (p.9). The composition further comprises the nutrients necessary to support growth of the microorganisms (p.3).

Although Townsend does not specifically teach the composition comprising tetrazolium red, Townsend does teach effective markers include tetrazolium. Therefore it would have been well within the purview of one of ordinary skill in the art to use tetrazolium red in the composition of Townsend with a reasonable expectation for successfully detecting microorganisms.

7. Claims 1 – 8 and 10 – 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over s Townsend in view of Stern.

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Applicant claims a composition comprising a conditionally detectable marker that provides a detectable signal upon contact with a viable microorganism, and a substrate for an aminopeptidase that is substantially absent from a target microorganism. The target microorganism is a bacteria, yeast, mold, fungi, protozoa or virus, specifically bacteria selected from Salmonella, Listeria, E. coli OH157, Campylobacter, Staphylococcus aureus, Cryptosporidium or Giardia. The preferred bacteria are Campylobacter. The conditionally detectable marker is detectable by a color change, wherein the change in color is produced by a biochemical reduction of tetrazolium red. The substrate comprises a signal moiety linked to the substrate that provides a detectable signal when cleaved by substantially all non target microorganisms. The aminopeptidase is specifically L-alanine aminopeptidase; and the substrate is selected from a disclosed group, specifically L-alanine-7-amido-4-methylcoumarin. The non-target microorganisms are substantially all non-Campylobacter species. The composition further comprises a growth supporting medium for target microorganisms, which contains all necessary nutrients and growth conditions to support target organism and antibiotics to suppress growth of non target microorganisms.

Townsend teaches a composition for detecting viable bacteria, yeasts or fungi (p.11) in a test sample, the composition comprising substrates and detectable markers (abstract). Townsend teaches examples of detectable markers include tetrazolium that is chemically reduced to produce a color change (p.2) and bacterial substrates that change color or fluoresce upon bacterial hydrolysis (p.6, 9), or are conditionally detectable markers. Bacteria are selected from Staphylococcus aureus, E. coli, and gram negative bacteria of Bergey's Manual of Systematic Bacteriology, 1989 (p.8-9) (includes Salmonella, Listeria, Campylobacter, Cryptosporidium, S.

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aureus). Townsend teaches the claimed substrates (p.19), preferring L-alanine-7-amido-4-methylcoumarin, and L-alanine-aminopeptidase as the enzyme (p.9). The composition further comprises the nutrients necessary to support growth of the microorganisms (p.3).

Although Townsend does not specifically teach the composition comprising tetrazolium red, Townsend does teach effective markers include tetrazolium. Therefore it would have been well within the purview of one of ordinary skill in the art to use tetrazolium red in the composition of Townsend with a reasonable expectation for successfully detecting microorganisms.

Townsend does not teach the composition further comprising antibiotics. However, Stern teaches compositions for detecting viable gram negative bacteria comprising antibiotics for suppressing other, non target microorganisms (abstract). Stern teaches the inclusion of antibiotics allows the characterization of the target microorganism (col.1 line 25-36). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Stern to include antibiotics in the composition of Townsend with a reasonable expectation for successfully detecting viable target bacteria.

Applicant argues that Townsend uses the compositions to detect different organisms that applicant and that the examiner uses improper hindsight.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the

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time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Regarding the use of the composition, while Townsend does not teach that the composition can be used in the manner instantly claimed, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

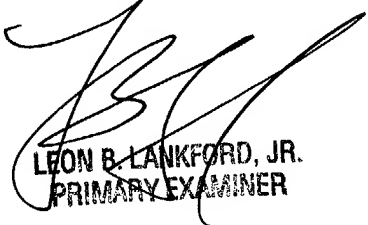
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Effective January 20, 2004, any inquires should be made to Ruth Davis whose telephone number is 571-272-0915. The examiner's supervisor, Michael Wityshyn, can be reached at 571-272-0926.

Ruth A. Davis; rad
December 22, 2003.



LEON B. LANKFORD, JR.
PRIMARY EXAMINER